

## Food and Drug Administration, HHS

## § 520.100c

percent level); continue with 0.006 percent amprolium-medicated water for an additional 1 to 2 weeks; no other source of drinking water should be available to the birds during this time; as sole source of amprolium.

(2) *Calves*—(i) *Amount*. 9.6 percent solution or 20 percent soluble powder.

(a) *Indications for use*. As an aid in the treatment of coccidiosis caused by *Eimeria bovis* and *E. zurnii*.

(b) *Limitations*. Add 16 fluid ounces of the 9.6 percent solution to each 100 gallons of drinking water; or 4 ounces of the soluble powder to each 50 gallons of drinking water; at the usual rate of water consumption, this will provide an intake of approximately 10 milligrams per kilogram (2.2 pounds) of body weight; offer this solution as the only source of water for 5 days; for a satisfactory diagnosis, a microscopic examination of the feces should be done by a veterinarian or diagnostic laboratory before treatment; when treating outbreaks, the drug should be administered promptly after diagnosis is determined; withdraw 24 hours before slaughter.

(ii) *Amount*. 9.6 percent solution or 20 percent soluble powder.

(a) *Indications for use*. As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii*.

(b) *Limitations*. Add 8 fluid ounces of the 9.6 percent solution or 4 ounces of the 20 percent soluble powder to each 100 gallons of drinking water; at the usual rate of water consumption, this will provide an intake of approximately 5 milligrams per kilogram (2.2 pounds) of body weight; offer this solution as the only source of water for 21 days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard; withdraw 24 hours before slaughter.

[40 FR 13838, Mar. 27, 1975, as amended at 62 FR 63270, Nov. 28, 1997]

### § 520.100b Amprolium drench.

(a) *Chemical name*. 1-(4-Amino-2-n-propyl - 5 - pyrimidinylmethyl) - 2 - picolinium chloride hydrochloride.

(b) *Sponsor*. See No. 050604 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.50 of this chapter.

(d) *Conditions of use*. It is used for calves as follows:

(1) *Amount*. 9.6 percent solution or 20 percent soluble powder.

(i) *Indications for use*. As an aid in the treatment of coccidiosis caused by *Eimeria bovis* and *E. zurnii*.

(ii) *Limitations*. Add 3 fluid ounces of the 9.6 percent solution to 1 pint of water or 3 ounces of the 20 percent soluble powder to each quart of water and with a dose syringe administer 1 fluid ounce of this solution for each 100 pounds of body weight; this will provide a dose of approximately 10 milligrams per kilogram (2.2 pounds) of body weight; administer daily for 5 days; for a satisfactory diagnosis, a microscopic examination of the feces should be done by a veterinarian or diagnostic laboratory before treatment; when treating outbreaks, the drug should be administered promptly after diagnosis is determined; withdraw 24 hours before slaughter.

(2) *Amount*. 9.6 percent solution or 20 percent soluble powder.

(i) *Indications for use*. As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii*.

(ii) *Limitations*. Add 1½ fluid ounces of the 9.6 percent solution to 1 pint of water or 1½ ounces of the 20 percent soluble powder to each quart of water and with a dose syringe administer 1 fluid ounce of this solution for each 100 pounds of body weight; this will provide a dose of approximately 5 milligrams per kilogram (2.2 pounds) of body weight; administer daily for 21 days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard; withdraw 24 hours before slaughter.

[40 FR 13838, Mar. 27, 1975, as amended at 62 FR 63270, Nov. 28, 1997]

### § 520.100c Amprolium crumbles.

(a) *Specifications*. Amprolium crumbles contain 1.25 percent amprolium.

(b) *Sponsor*. See No. 050604 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.50 of this chapter.

(d) *Conditions of use*. It is top-dressed on or thoroughly mixed in the daily feed ration of calves as follows:

(1) *Amount*. 1.6 ounces of crumbles per 250 pounds of body weight per day (5

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milligrams per kilogram of body weight).

(i) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii*.

(ii) *Limitations.* Administer for 21 consecutive days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard. Withdraw 24 hours before slaughter. Use as sole source of amprolium.

(2) *Amount.* 3.2 ounces of crumbles per 250 pounds of body weight per day (10 milligrams per kilogram of body weight).

(i) *Indications for use.* As an aid in the treatment of coccidiosis caused by *Eimeria bovis* and *E. zurnii*.

(ii) *Limitations.* Administer for 5 consecutive days. For satisfactory diagnosis, a microscopic fecal examination should be done by a veterinarian or diagnostic laboratory before treatment. When treating outbreaks, the drug should be administered promptly after diagnosis is determined. Withdraw 24 hours before slaughter. Use as sole source of amprolium.

[42 FR 41855, Aug. 19, 1977, as amended at 62 FR 63270, Nov. 28, 1997]

## § 520.110 Apramycin sulfate soluble powder.

(a) *Specifications.* A water soluble powder used to make a medicated drinking water containing apramycin sulfate equivalent to 0.375 gram of apramycin activity per gallon of drinking water.

(b) *Sponsor.* See No. 000986 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.52 of this chapter.

(d) *Conditions of use.* (1) In swine for control of porcine colibacillosis (weanling pig scours) caused by strains of *E. coli* sensitive to apramycin.

(2) It is administered for 7 days in drinking water at the rate of 12.5 milligrams of apramycin per kilogram (5.7 milligrams per pound) of body weight per day. Swine will normally consume 1 gallon per day of medicated water containing 375 milligrams of apramycin for each 66 pounds of body weight. Water consumption should be monitored to determine that the required amount of apramycin is being consumed. The drug concentration

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should be adjusted according to water consumption which varies depending on ambient temperature, humidity, and other factors.

(3) Prepare fresh medicated water daily.

(4) Do not slaughter treated swine for 28 days following treatment

[47 FR 15771, Apr. 13, 1982, as amended at 49 FR 19642, May 9, 1984; 53 FR 37753, Sept. 28, 1988]

## § 520.154 Bacitracin oral dosage forms.

### § 520.154a Soluble bacitracin methylene disalicylate.

(a) *Specifications.* Each pound of soluble powder contains the equivalent of 50 grams of bacitracin activity for use as in paragraph (d)(1) or (d)(2) of this section, or the equivalent of 200 grams of bacitracin activity for use as in paragraph (d) of this section.

(b) *Sponsor.* See No. 046573 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.70 of this chapter.

(d) *Conditions of use*—(1) *Growing turkeys*—(i) *Amount.* 400 milligrams per gallon in drinking water.

(ii) *Indications for use.* Aid in the control of transmissible enteritis complicated by organisms susceptible to bacitracin methylene disalicylate.

(iii) *Limitations.* Prepare a fresh solution daily.

(2) *Broiler and replacement chickens*—(i) *Amount.* 100 milligrams per gallon in drinking water.

(A) *Indications for use.* Aid in the prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to bacitracin methylene disalicylate.

(B) *Limitations.* Prepare a fresh solution daily.

(ii) *Amount.* 200 to 400 milligrams per gallon in drinking water.

(A) *Indications for use.* Aid in the control of necrotic enteritis caused by *C. perfringens* susceptible to bacitracin methylene disalicylate.

(B) *Limitations.* Prepare a fresh solution daily.

(3) *Swine*—(i) *Amount.* 1 gram per gallon in drinking water.

(ii) *Indications for use.* Treatment of swine dysentery associated with *Treponema hyodysenteriae*. Administer